Legislation on clinical trials

2112. SHRIMATI MOHSINA KIDWAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether various women organizations in the country have demanded strengthening of legislation related to clinical trials of new drugs;

(b) if so, the details thereof;

(c) whether such organizations have raised concern over implementation of the good clinical practice guidelines and ethical norms; and

(d) if so, the steps Government propose to take to make the condition for clinical trials more stringent and introduce clear guidelines or compensation?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) The Drug Controller General (India) has informed that his office has not received any representation from women organizations in the country demanding strengthening of legislation related to clinical trials of new drugs. However, during deliberations among various stakeholders like industry associations, NGOs, experts, regulators etc. on the proposed amendment of Schedule Y to Drugs and Cosmetics Rules, some NGOs mentioned that Good Clinical Practice (GCP) guidelines and ethical norms should be strengthened and properly implemented in the country.

(d) Schedule Y already provides the requirements and guidelines for Clinical trials, which mandates that trial should be conducted as per GCP guidelines, Para 2.4.7 of GCP guidelines prescribes the provision for providing compensation by the sponsor in case of injury caused to the trial subjects. Schedule Y also prescribes responsibility of sponsor, investigator and ethics committee to safeguard the right safety and well being of the trial subjects. However, the following steps are under consideration of the office of Drug Controller General of India to make the condition for clinical trials more stringent:-

1. Good Clinical Trial Practice Inspection

2. Registration of Clinical Research Organization

3. Mandatory Clinical Trial Registration, which is currently advisory in nature.

Per head expenditure on health

2113. SHRI VIJAY JAWAHARLAL DARDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware of the WHO study pointing out that in India, the per head total expenditure is 91 US dollars and average surgical rate (for 1,00,000 population) is 369 dollars whereas in China it is 277 dollars and 2659 dollars respectively;

(b) if so, what was the financial allocations for health sector in 2006 and 2007 and whether these were fully utilized; and